K063181

SYNTHES®

3.0 510(k) Summary

Sponsor:
Synthes (USA)
1301 Goshen Parkway
West Chester, PA 19380
(610) 719-5000

JAN - 5 2007

Device Name: Synthes (USA) Condylar Head Add-on System

Classification: 21 CFR 872.3960: Mandibular condyle prosthesis

Predicate Devices: Synthes Locking Reconstruction Plate (LRP) with Condylar Head (K990637)
Stryker Leibinger, Attachable Condylar Head (K020199)

Device Description: The Synthes (USA) Condylar Head Add-on System is an adjustable height system intended for use with Synthes' 2.4 mm Locking Reconstruction Plate (LRP) System. The system consists of an elliptical shaped condylar head, four different fixation plates which allow the surgeon to adjust the height of the condylar head, and two fixation screws for mounting the condylar head and fixation plate onto a 2.4 mm locking reconstruction plate.

Intended Use: Intended for temporary reconstruction in patients undergoing ablative tumor surgery requiring the removal of the mandibular condyle. This device is not for permanent implantation, for patients with TMJ or traumatic injuries, or for treatment of temporomandibular joint disease (TMD).

Substantial Equivalence: Information presented supports substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 9 - 2008

Ms. Deborah L. Jackson
Regulatory Affairs Specialist
Synthes (USA)
1301 Goshen Parkway
West Chester, Pennsylvania 19380

Re: K063181
Trade/Device Name: Synthes (USA) Condylar Head Add-on System
Regulation Number: 872.3960
Regulation Name: Mandibular Condyle Prosthesis
Regulatory Class: III
Product Code: NEI
Dated: October 18, 2006
Received: October 19, 2006

Dear Ms. Jackson:

This letter corrects our substantially equivalent letter of January 5, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

2.0 Indications for Use

510(k) Number (if known): K063181

Device Name: Synthes (USA) Condylar Head Add-on System

Indications for Use: Intended for temporary reconstruction in patients undergoing ablative tumor surgery requiring the removal of the mandibular condyle. This device is not for permanent implantation, for patients with TMJ or traumatic injuries, or for treatment of temporomandibular joint disease (TMD).

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K063181